

PROSBEN INC.

Tel: 886-2-2500 0586, Fax: 886-2-2500 0945

Add.: 11F, No.58, Ming Chuan East Road, Sec.3, Taipei 104, Taiwan

PROSBEN

NEW VISION BEGIN WITH

MAY 31 2013

K122700

II. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

2.1. General Information Establishment

- Manufacturer: **PROSBEN INC.**
- Address: 11F., No.58, Sec. 3, Mingchaun East Road, Taipei, 10477, Taiwan, R.O.C.
- Owner Number: **8022656**
- Contact Person: Dr. Jen, Ke-Min E-mail: ceirs.jen@msa.hinet.net
(Tel) +886-3-5208829 ; (Fax) +886-3-5209783
- Date Prepared: August 23, 2012

Device

- **Proprietary Name:** PROSBEN Contact Lens Cases;
CA66-02, CA66-03WB, CA66-04T series
- **Common Name:** Contact Lens Case
- **Classification Name:** Case, Contact Lens
- **Product Code:** LRX, Class II, 886.5928

2.2. Safety and Effectiveness Information

- **Predicate Device:**
Claim of Substantial Equivalence (SE) is made to i-Promotions Contact Lens Case (K042578)
- **Device Description:**
The PROSBEN Contact Lens Case is the subject of this 510(k) premarket notification. The Contact Lens Case is a lens care product to be used the contact lens wearer or practitioner for storing contact lenses while not being worn. The PROSBEN Contact Lens Cases are designed for use in chemical disinfection only; not to be used with heat. The PROSBEN Contact Lens Cases are not including the disinfection, only for shipping the cases in a dry state.
- **Summary of Safety Data:**
PROSBEN Contact Lens Cases completed the relevant test including:
 - 1) ISO 10993-5 Biological evaluation of medical devices, part 5: Test for in vitro cytotoxicity;
 - 2) ISO10993-10 Biological evaluation of medical devices, part 10: Test for irritation and skin sensitization;

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- 3) ISO10993-11 Biological evaluation of medical devices, part 11: Test for system toxicity;
- 4) The materials are complied with the biological and toxicology evaluation and the results of these studies show that the Contact Lens Cases are safety for its intended use.

● **Intended Use:**

The PROSBEN Contact Lens Cases are intended for storage during chemical disinfection of soft (hydrophilic), rigid gas permeable and hard contact lenses. For use during chemical disinfection only; not to be used with heat.

● **Substantial Equivalence (SE)**

A claim of substantial equivalence is made to i-Promotions Contact Lens Case (K042578). Both of them have the same indications for use, working principle and technologies. The major differences of the two devices are due to the different designed for adjoining wells with integral hinged caps or screw-top caps, and used the different PP or PE material with different color additives; please refer to the below "Comparison Table". These are not relating to the safety or effectiveness aspects. Thus they are substantially equivalent.

Comparison Table

Comparison Feature	i-Promotions Contact Lens Case (K042578)	PROSBEN Contact Lens Cases series (K122700)
Design	Two adjoining wells with integral hinged caps into which respective lenses are immersed.	hinged caps: CA66-04T series screw-top caps: CA66-02 and CA66-03WB series
Materials	Low density Polyethylene #9931 with five colorants.	PP (CAS# 9003-07-0): CA66-02 and CA66-03WB series PE (CAS# 9002-88-4): CA66-04T series with colorants: white, blue, green



Dr. Jen, Ke-Min

510K correspondent person for
PROSBEN INC.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

May 31, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Dr. Jen, Ke-Min
Prosben, Inc.
11F, No. 58, Sec. 3
Mingchaun East Road
Taipei
China (Taiwan) 104

Re: K122700

Trade/Device Name: Prosben Contact Lens Cases, CA66-02, CA66-03WB,
and CA66-04T Series

Regulation Number: 21 CFR 886.5928

Regulation Name: Case, Contact Lens

Regulatory Class: Class II

Product Code: LRX

Dated: May 11, 2013

Received: May 22, 2013

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate

commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose

and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510 (K) Number (If Known): K122700

Device Name: Contact Lens Cases; CA66-02, CA66-03WB, CA66-04T series

Indications for Use:

The PROSBEN Contact Lens Cases are intended for storage during chemical disinfection of soft (hydrophilic), rigid gas permeable and hard contact lenses.

For use during chemical disinfection only; not to be used with heat.

Prescription Use _____
(21 CFR Part 801 Subpart D)

AND/OR

Over the Counter Use ✓
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Claudine H. Krawczyk
2013.05.30 13:27:35-04:00'